EXHIBIT I

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION
Master File No. 2:12-MD-02327
MDL No. 2327

JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO ALL

WAVE VI CASES:

DEPOSITION OF

RALPH ZIPPER, M.D.

Friday, October 27, 2017
12:17 p.m. - 2:57 p.m.

Hilton Melbourne Rialto Place
200 Rialto Place
Melbourne, Florida 31901-3092

Stenographically Reported By:
Lisa G. Smith, RMR

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BY MR. WALKER:

Q. Other than medical literature and company documents, what other materials did you review when you were formulating your opinions on TVT-Secur?

MR. THORNBURGH: Objection. There's things in addition to medical literature and internal corporate documents.

BY MR. WALKER:

Q. That's what I'm asking. I'm asking what are those other categories of documents?

A. I'll do my best to answer your question. My opinion is based not only on the internal documents of Ethicon, including but not limited to their memorandums, their PowerPoint presentations, their emails, their guidance documents, the medical literature that pertains to products relevant to this opinion, but also my years of knowledge, training and experience as both a pelvic surgeon and as an inventor of medical devices and as an executive working as a consultant to medical device companies and as an executive running medical device companies. Those are an example of things that were used to formulate my opinion, but not necessarily the comprehensive list of all things.

Q. Doctor, I've marked as Exhibit No. 6 a copy

there any others that you perform?

MR. THORNBURGH: Objection.

THE WITNESS: Lisa, can you please read back my answer?

BY MR. WALKER:

Q. Your answer involved non-surgical treatment options for stress urinary incontinence. I'm just trying to establish, Doctor, a list of strictly the surgical options that you provide your patients with.

A. Well, if Lisa read back my answer, you would --

MR. THORNBURGH: That's a different question than was originally asked.

A. However, I offer my patients procedural options that include transurethral bulking agent implantation, that include the sling surgeries, midurethral sling surgeries performed with synthetic material, as well as natural materials such as xenograft, allograft and autograft surgery.

BY MR. WALKER:

Q. What synthetic materials do you use when you surgically treat stress urinary incontinence?

MR. THORNBURGH: Objection.

A. I presently in a select group of patients, a small select group of patients, will offer them a

polypropylene mesh full-length midurethral sling.

BY MR. WALKER:

Q. And what product?

A. Whatever midurethral sling the surgical center or hospital has.

Q. Would that include the TVT retropubic full-length sling?

A. No.

Q. Are you able to recall any specific manufacturer that your facility provides?

A. Supplies have changed recently, but there was a time before I learned through the suffering injury of my patients and the chagrin of my peers of the complications that are associated with slings and therefore, as I did, I informed my patients. Less and less patients wanted slings.

So at one point in my career, I was doing well over a hundred slings a year. Maybe at this point I'm doing five or 10. Over the last year or two, those slings may have been manufactured by companies such as American Medical Systems and Boston Scientific.

Q. Doctor, would you agree that if you are providing as a treatment option a retropubic full-length synthetic sling, that it is within the standard of care to treat a patient for stress urinary

at their polypropylene mesh and the end results of the process you're describing. So though I could not describe to you the antioxidant material used to inhibit degradation in the TVT-S sling, I have had the opportunity to look at the end result.

BY MR. WALKER:

Q. Would you agree with me that the mesh material of TVT-Secur is the same mesh material that's used in TVT retropubic and the TVT-O with the exception perhaps of how it's cut?

MR. THORNBURGH: Objection. I think it's a significant exception.

THE WITNESS: Could you please read back the question?

(The question on page 32, line 7, was read back.)

A. With the exception of how it's cut, with the exception of how it is shaped, and with the exception of the pieces that are added to it, it is my understanding that the base material, polypropylene is the same.

BY MR. WALKER:

Q. My question is a little more specific. The mesh itself, the weave of the mesh, the mesh material, would you agree that it's the same in all three

products?

MR. THORNBURGH: Objection, asked and answered.

A. When you originally asked the question, you attached it to an exception and so my answer provided that there are additional exceptions, and so you excepted the fact that it was cut differently and I want everyone who might read this transcript to understand that there are other exceptions that need to be considered as well.

But once again, if you're asking about the substrate and the resin and the polypropylene fiber that is extruded, it is my understanding that they're the same.

BY MR. WALKER:

Q. Let me try it this way: Would you agree that the pore size of the TVT-Secur mesh is the same as the pore size of the TVT retropubic and TVT-O?

A. I would -- it is my understanding that even scientists within Ethicon could not confidently agree with that because uniformity of fabrication was compromised and pore size varied even in one sheet of material.

But it is my understanding that the fabrication process was the same and the resin was the

short. The initial TVT-X sling was 12 centimeters compared to a 48-centimeter TVT.

Well, we know that scaring takes place around the sling. That's how you get durable fixation and we know that the amount of fixation is proportional to the amount of material of which the scar occurs around. So when you place an eight centimeter sling in, you need an even better fixation device, a better fixation mechanism, instead of no fixation mechanism.

So there's -- the length was most likely -- more likely than not defective. The fixation means was defective. The inserter was defective. The inserter was so defective that key opinion leader Dr. Jaime Sepulveda dedicated 16 of his 29 slide lecture just to talking about how to take out the darn inserter.

The laser cutting of the product was defective, and this is just not my opinion this is the opinion of some of the Ethicon's key opinion leaders including Dr. Newman. Dr. Newman opined that the stiff laser cut edges were responsible for vaginal pain and the high erosion rates.

There is additional discussion of design and method defects that is described in my written opinion. There are.

Q. Doctor, what if any experience do you have in

device labeling?

A. Early on -- in the middle of my career in or about 2006, 2007, I as a consultant began writing labeling for pelvic organ prolapse and mesh products and sling products, but more recently, have been intimately involved in the creation of the labels for both of my companies which are in the process of coming to market with two devices in the women's health space that already have 510(k) clearances, but we are submitting a sub Q application for both an IDE and randomized control trials for new indications for use and those applications are associated with new labels and I'm in the process of writing those labels.

Q. Doctor, what if any methodology did you use in rendering your warning and labeling opinions?

A. So my method, which improves as all things do over time, my method relies on the FDA guidance, which includes the Code of Federal Regulations, Part 801, the adjoining guidance G91-1, includes the ISO guidance, including 14 630.

So my method begins by I open up all those pages. I open up the FDA guidance, I opened up the ISO guidance. I apply that to the development of my label. That's where my minimum requirements begin.

But ultimately, when you're going to be

selling a device for the treatment of human beings, in this case women, you can't do the minimal. You want to try to do the maximum.

And so after I make sure that I meet the minimum requirements and if we look at G91-1 guidance to the original code of CFR 801, once I ensure that I've met those minimum requirements and I create an adequate label and I'm not ambiguous, and I make sure that I use terms for a patient label that patients can understand, and I make sure that I inform what is known and what is not known and what clinical trials are missing and what clinical trials we have and what different opinions we have, I test that label first among my coworkers and then once they're done, it'll be tested among the end users.

And let me tell you, the end users are not key opinion leaders. That's not our intended user. It's the world of generalists. So although we may ask key opinion leaders to be part of design validation, design validation of these labels will include enough true users of the device. That's the only way that you can adequately test a label.

So my method starts off the minimum requirements, which are defined in the code of federal regulations and in the guidance documents and in the

ISO documentation and then improve on that, get input from the real end users and make sure the labels are adequate to accomplish what a label needs to accomplish to inform users and patients and make sure the device can be used safely and effectively for its intended use.

Q. That methodology that you just described, do you use that methodology in your practice as a CEO executive board member of device manufacturing companies?

A. Absolutely.

Q. Doctor, do you have an opinion one way or the other whether or not a sutured device for treatment of stress urinary incontinence is a safer, more -- a safe alternative design?

A. Yeah, absolutely. I believe that there was a systematic review of the literature in 2009 and/or 2011 by the Cochrane Group that compared the efficacy of sutured-device type repairs such as the Burch procedure, conventional slings and midurethral slings and those systematic reviews found that all three procedures, the suture-device-type repair, the Burch repair, the traditional sling, and the synthetic midurethral sling all had similar efficacy, so they were all equally effective.

There was some -- what they call variable and low level evidence to suggest that the synthetic repair had less short-term urinary tract symptoms, but there was no evidence of any long-term benefit from any one of those procedures over the other. So in the long term, the suture-device repair and the classical natural tissue sling repairs were equally effective and more likely than not safer.

Q. Doctor, do you have an opinion whether or not a full-length midurethral sling mechanically cut using Ultrapro would have been a safer alternative design than the TVT-Secur device?

A. It would have been safer.

Q. As a CEO or an executive and board member of medical device manufacturing companies, do you have an opinion one way or the other whether or not Ethicon and Johnson & Johnson acted as a prudent manufacturer could have acted in manufacturing, designing, selling and labeling the TVT-Secur device?

A. Yes, I do.

Q. What's that opinion?

A. My opinion is that Ethicon slash Johnson & Johnson took unacceptable shortcuts and thereby failing to provide safety and efficacy for the devices subject to today's deposition, the TVT-Secur device.